

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed January 13, 2009 have been fully considered but they are not persuasive. The Applicant, in addition to arguing that Kahn et al. does not teach a telescopic relationship of the inflow tube and adjustable member, argues "that the spirally wound metal wire" of Kahn et al. is not "a spring".

The previous rejection stated, "Furthermore, since the "arterial graft tubings 87 and 92 are made of flexible, non- collapsing materials, for example, spirally wound metal wire covered with silicone" (col. 6, lines 37-39) they are thus flexible and compressible and can be extended or retracted".

Regardless, even if the spirally wound metal wire" of Kahn et al. is not "a spring", it would still remain capable of being compressed or extending in the longitudinal plane, thus permitting the modification of the adapter sleeve length.

Even though the applicant's arguments have not been found persuasive, new grounds of rejection have been set forth in response to the amendments to the claims.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-10 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 12 recite the limitations “telescopic relationship” and “telescopically”. There is no description of telescopic or telescoping interactions between the components. The specification merely has support for an “attachment means may include an adjustable member to cause the sleeve 160 to extend or retract from the end of the inflow tube 146” (original specification, page 9, lines 9-10) and does not mention the “telescopic relationship”.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-3, 7-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kahn et al. (US 3,766,567). Kahn et al. discloses an artificial heart assembly that is connected to the ventricular apex of the heart, as seen in figure 8. Also depicted in figure 8 is the pump 20, inflow adapter 88 which the examiner considers the inflow tube, tubular extension 86 which the examiner considers to be an adapter sleeve,

and arterial grafting tubing 87 which the examiner considers to be the adjustable attachment member.

Furthermore, since the “arterial graft tubings 87 and 92 are made of flexible, non-collapsing materials, for example, spirally wound metal wire covered with silicone” (col. 6, lines 37-39) they are thus flexible and compressible and can be extended or retracted, thus permitting the modification of the adapter sleeve length.

Kahn et al. discloses the device substantially as claimed except for the telescopic relationship bettering the inflow tube and the adapter sleeve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the adapter sleeve to slide over, or have a telescopic relationship with, the inflow tube in order to quickly and effectively modify the length of the inflow tube in order to provide the predictable results of modifying the ventricular assist device to meet specific patient needs and requirements, such as patient size (i.e. child or adult).

As to claims 2-3 and 7, also seen in figure 8 is the sewing flange 76. Furthermore, the examiner considers the sewing ring to function as a gripping member to attach the inflow tube to the ventricular apex.

As to claim 8, as seen in figure 8, since the inlet and outlet of the inflow tube are at different angles, there is necessarily a bend in the tube.

As to claims 9-10, “built into the assist adapters 88 and 89 are connectors 90 and 91 like the connector 22 of FIGS. 6 and 7 for easy attachment to the connectors 23 and 27 on the ventricle 11”(col. 6, lines 31-33). Thus the end of inflow tube 88 that connects to connector 90 is extendable, as seen in figures 6 and 7. Furthermore the examiner

considers the connection to be rotatable since the connectors can be rotated to facilitate engagement.

As to claim 11, figure 6 discloses a valve 21, which the examiner considers to be an inner sleeve.

2. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Kahn et al. as applied to claims 1-4, 6-10 and 12 above. The modified Kahn et al. discloses the claimed invention but does not disclose expressly the titanium or ceramic material. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the adapter sleeve as taught by the modified Kahn et al., with a titanium or ceramic adapter sleeve, because Applicant has not disclosed the titanium or ceramic material provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the adapter sleeve as taught by the modified Kahn et al., because both materials are biocompatibility and frequently incorporated in implantable devices.

Therefore, it would have been an obvious matter of design choice to modify the material for titanium to ceramic to obtain the invention as specified in the claim(s).

Furthermore, the modified Kahn et al., discloses the claimed invention except for the titanium or ceramic material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material to ceramic material, since it has been held to be within the general skill of a worker in the art to select a

known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416 (See MPEP 2144.07)

3. Claim 5 stands rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Kahn et al. as applied to claims 1-4, 6-10 and 12 above. The modified Kahn et al. discloses the claimed invention except perforations on the adapter sleeve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of the modified Kahn et al. with grooves forming perforations in order to provide the predictable results of customizing the size of the adapter sleeve in order to modify the device to meet specific patient needs. For example, a child may need an adapter that differs in size than an adult, so having one device that can be used for either adult or child is advantageous.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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